C.F. ELECTRONICS
MEDICAL TECHNOLOGY DIVISION

MAY 14 1996

K955659

ELECTRONICS, INC. • 5 Brayton Court • Commack, NY 11725 • Tel: 516-499-8085 • Fax: 516-499-8657

510(k) SUMMARY

DRUGBOX MODEL MC-2000

C.F. Electronics, Inc. is requesting marketing clearance for its Temperature-controlled drug case, which will be manufactured by Koolatron Division of Urus Industrial Corporation and marketed by C.F. Electronics, Inc. The Premarket Notification information required by 21 CFR 807.87 is as follows:

a. Classification Name: Drug case, Temperature controlled
Common/Usual Name: Temperature controlled drug box
Proprietary Name: DRUG BOX MC-2000 (Part Number 203045)

b. Establishment Registration Number: 2435731

c. Classification: Not determined. Manufacturer believes device should be exempt or Class I

d. Performance standards: Not applicable

e. Substantial equivalence: The MC-2000 is similar to the C.F. Electronics Therm-O-Drug [510(k) No. K922786]. That device uses low intensity, low voltage resistance heaters with thermostatic control to warm drugs in an insulated enclosure.

Contact person: Robert P. Freedman

Date summary prepared: December 7, 1995

DESCRIPTION OF DEVICE

Purpose:

The DrugBox MC-2000 is designed to maintain medications at their recommended storage temperature over a wide range of ambient temperatures. Recent publications (see citations) have shown that several of the drugs commonly used in emergency medical service lose potency or even are totally unusable after exposure to temperatures outside the recommended storage range.

Since ambulances and back-up vehicles are frequently exposed to extreme ambient temperatures for extended periods, it is necessary to take precautions to keep the drug case and its contents within the correct storage temperature range.

In checking the labeling of every drug listed by a typical ambulance service for their drug box, we found the recommended storage temperature range to be 59-86° F (15-30° C) in every instance. The DrugBox MC-2000 will maintain the drugs in the correct temperature range; heating or cooling automatically, as required.

General description of the device:

The DrugBox MC-2000 is an insulated case with electronic temperature control. Heating or cooling is by means of a thermoelectric module, using the Peltier effect. The electronic control senses the temperature of air returning to the internal heat sink, compares it to the set point, and directs current to the thermoelectric array to heat or cool as necessary to maintain the set point. Depending upon the user's requirements, internal spacers or a rack are provided to ensure that air can be circulated around the drugs.

In typical use, the DrugBox MC-2000 would be carried in the emergency vehicle and powered at all times. One or more complete kits of drugs will be kept in the DrugBox MC-2000 in soft cases and moved to the EMT's regular portable drug box for use. The DrugBox MC-2000 may also be used indoors or in any situation where 12VDC or 115VAC (power adapter required) is available.

Detailed description:

Dimensions [Inches/mm]	
Inside	12.5/317.5 H, 12/3.5 W, 12/305 D
Outside	15.5/394 H, 17.5/445 W, 16/406 D
Weight	12 lb/5.4 kg
Case construction	Polypropylene inner and outer shells, polyurethane foam insulation
Temperature controller	Solid-state with adjustable set-point and out-of -tolerance detection
Set-point adjustment	Recessed screwdriver slot
Active element	Thermoelectric module with circulating fan
Displays	Inside temperature (digital) In-tolerance LED Out-of-tolerance LED

Power requirement	12VDC @ 3-4 amperes
Power adapter (Part No. 203046)	115VAC input, 12VDC @ 4.5 amperes max. (UL and CSA listed)
Ambient temperature range	20°F to 120°F (-6.7 to 48.9°C)

(for interior temperature of 60°F to 84°F (15.5-28.9°C))

SUBSTANTIAL EQUIVALENCE COMPARISON

	MC-2000	THERM-O-DRUG
Function	Store drugs at 59-86°F/15-30°C	Store drugs above 59°F/15°C min.
Protect against low ambients	to 20°F/-6.7°C	to 10°F/-12.2°C
Protect against high ambients	to 120°F/48.9°C	86°F-no cooling capability
Usable Capacity	1,050 in^3/17.2L	800 in^3/13.2L (Approx.)
Thermal device	Thermoelectric heater-cooler	Resistance heater
Control method	Solid-state	Thermostats
Adjustments	Set point pot.	None
Power source	12VDC	12V DC or AC
Current	4 Amp max	2.3 Amp
Displays	Temperature (digital) LEDs (2)	None

SAFETY INFORMATION

Method of heating/cooling	Thermoelectric module with heat sinks and circulating fan.
Power source	12VDC @ 4 amperes. This voltage is not hazardous to personnel.

Power adapter	115VAC input, 12VDC output @ 4.5 amperes max. UL & CSA listed.
Power consumption	48 watts
Control means	Solid-state electronics sensing interior air temperature. Adjustable set-point
Out-of-tolerance indicators	Digital temperature display Red LED indicator
Electrical protection	Fuse
Patient shock hazard	None; voltage used is not hazardous, and patient does not contact device. Optional power adapter isolates device fron AC lines.
Sterility	Not involved; drugs are contained in their own packaging.

EFFECTIVENESS INFORMATION

Because the drugs typically used by emergency medical services are labelled for storage at 59-86°F (15-30°C), and this device is intended to keep drugs within that range over a range of ambient temperatures, effectiveness is a function of the ambient temperature extremes which can be withstood without allowing the drugs to leave the specified temperature range.

BASED ON THE MANUFACTURER'S TESTS....

At an ambient temperature of 120°F/48.9°C, the internal temperature will not exceed 84°F/28.9°C.

At an ambient temperature of 20°F/-6.7°C, the internal temperature will not drop below 60°F/15.6°C.

Between 30°F and 105°F (-1.1 to 40.6°C), the internal temperature can be maintained between 70° and 75°F (21.1 to 23.9°C).